K071985

AUG 17 2007

Attachment B

Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Section a):

1. Submitter: GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
PO Box 414
Milwaukee, WI 53201

Contact Person: Allen Schuh,
Manager, Ultrasound Regulatory Affairs
Telephone: 414-721-3992; Fax: 414-721-3899

Date Prepared: July 18, 2006

2. Device Name: GE Vivid S5/S6 Diagnostic Ultrasound System
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX

3. Marketed Device: GE Vivid 3 Ultrasound System, K020789 currently in commercial distribution.

4. Device Description: The GE Vivid S5/S6 is a mobile ultrasound console having a wide assortment of electronic array transducers intended primarily for echocardiography with additional capability in vascular a and general ultrasound imaging. Its intuitive user interface, high level of auto-optimization along with significantly reduced size and weight make it readily maneuverable, efficient and easy to use.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal; Transrectal; Transvaginal; and Intraoperative (abdominal, thoracic, and vascular).

6. Comparison with Predicate Device: The GE Vivid S5/S6 is of a comparable type and substantially equivalent to the currently marketed GE Vivid 3. Although it is somewhat smaller and lighter than Vivid 3, the overall construction, materials and performance as well as key safety and effectiveness features are equivalent. It has the same intended uses as the predicate device and includes transducers and features which are well established on other GE Vivid ultrasound systems.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and ISO13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE Vivid S5/S6 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2007

Mr. Allen Schuh
Manager, Ultrasound Regulatory Affairs
General Electric Co.
GE Healthcare
9900 Innovation Drive, Mail code-RP2138
WAUWATOSA WI 53226

Re: K071985
Trade Name: GE Vivid S5/S6 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 18, 2007
Received: July 19, 2007

Dear Mr. Schuh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Vivid S5/S6 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C-RS	3S-RS	9T-RS
8C-RS	5S-RS	P2D
E8C-RS	7S-RS	P6D
8L-RS	10S-RS	
12L-RS	6T-RS	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled,

"Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

for NCB

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Attachment E

Indications for Use Forms

Indications for use forms are provided for the overall system and for each transducer. Use/mode combinations designated as "P" were previously cleared with the unmodified Vivid 3. "E" represents use/mode combinations added to the Vivid 3 via Appendix E of the guidance. Transducers which have the miniature connector (with the "-RS" suffix), but with identical scan-heads and performance are considered to be the same as their full-size connector version.

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	N	
Abdominal [1]	P	P	P	P	P	P	P	P	P	N	
Pediatric	P	P	P	P	P	P	P	P	P	N	
Small Organ (specify)[2]	P	P	P		P		P	P	P	N	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	N	
Adult Cephalic	P	P	P	P	P	P	P	P	P	N	
Cardiac[3]	P	P	P	P	P	P	P	P	P	N	
Peripheral Vascular	P	P	P	P	P		P	P	P	N	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	N	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	N	
Other[4]	P	P	P	P	P	P	P	P	P	N	
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	N	
Transrectal	P	P	P		P		P	P	P	N	
Transvaginal	P	P	P		P		P	P	P	N	
Transurethral											
Intraoperative (specify)[5]	P	P	P		P		P	P	P	N	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071985

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 4C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N		N		N	N	N	N	
Abdominal[1]	N	N	N		N		N	N	N	N	
Pediatric	N	N	N		N		N	N	N	N	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	N	N	N		N		N	N	N	N	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071985

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	N	N	N		N		N	N	N	N	
Pediatric	N	N	N		N		N	N	N	N	
Small Organ (specify)[2]	N	N	N		N		N	N	N	N	
Neonatal Cephalic	N	N	N		N		N	N	N	N	
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	N	N	N		N		N	N	N	N	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071985

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with E8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N		N		N	N	N	N	
Abdominal[1]	N	N	N		N		N	N	N	N	
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	N	N	N		N		N	N	N	N	
Exam Type, Means of Access											
Transesophageal											
Transrectal	N	N	N		N		N	N	N	N	
Transvaginal	N	N	N		N		N	N	N	N	
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J W Lamp

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071985

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 8L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	N	N	N		N		N	N	N	N	
Pediatric	N	N	N		N		N	N	N	N	
Small Organ (specify)[2]	N	N	N		N		N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	N	N	N		N		N	N	N	N	
Musculo-skeletal Conventional	N	N	N		N		N	N	N	N	
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J Whang

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071985

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/6 with 12L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P		P	P	P	N	
Small Organ[2]	P	P	P		P		P	P	P	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P		P	P	P	N	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	N	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	N	
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative [5] (specify)	P	P	P		P		P	P	P	N	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071985

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 3S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	N	
Abdominal[1]	P	P	P	P	P	P	P	P	P	N	
Pediatric	P	P	P	P	P	P	P	P	P	N	
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	N	
Cardiac[3]	P	P	P	P	P	P	P	P	P	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P	P	P	P	P	P	P	N	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071985

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 5S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	N	
Abdominal[1]	P	P	P	P	P	P	P	P	P	N	
Pediatric	P	P	P	P	P	P	P	P	P	N	
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	N	
Cardiac[3]	P	P	P	P	P	P	P	P	P	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071985

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 7S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
Anatomy/Region of Interest	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P	P	P	P	P	P	P	N	
Pediatric	P	P	P	P	P	P	P	P	P	N	
Small Organ (specify)[2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	N	
Adult Cephalic											
Cardiac[3]	P	P	P	P	P	P	P	P	P	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P	P	P	P	P	P	P	N	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

JWhang

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071985

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 10S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P	P	P	P	P	P	P	N	
Pediatric	P	P	P	P	P	P	P	P	P	N	
Small Organ (specify)[2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	N	
Adult Cephalic	P	P	P	P	P	P	P	P	P	N	
Cardiac[3]	P	P	P	P	P	P	P	P	P	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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510(k) Number K071985

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 6T-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	P	P	P	P	P	P	P	P	P	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	N	
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 9T-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	E	E	E	E	E	E	E	E	E	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	E	E	E	E	E	E	E	E	E	N	
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with P2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with P6D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
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[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[♦] Coded Pulse includes B-flow, Coded Harmonics and Coded phase inversion.

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